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EXAMINER	
TYSON, MELANIE RUANO	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	**Application No.** 10/681,695	**Applicant(s)** EIBSCHITZ-TSIMHONI, MAYA	
	Examiner Melanie Tyson	**Art Unit** 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *4,10,14,22 and 27-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-9,11-13,15-21 and 23-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date *10/7/2003*.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, Species III, in the reply filed on 18 August 2003 is acknowledged. The requirement is made FINAL.

2. Claims 4, 10, 14, 22, and 27-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species and there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 18 August 2006.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-3, 5-9, 13, 15-21, and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smirmaul (Patent No. 4,766,897) in view of Anis (Patent No.5,492,528).

Regarding claim 1, Smirmaul discloses an instrument for incising intraocular tissue (excision of the anterior lens capsule; column 1, lines 54-55) comprising a handle (Figure 1, elements 12/16), and a head portion (18) attached to the handle (12/16). Figure 2 shows the head portion (18) defines a plane and has a cutting edge (20) that extends from the head portion (18) in a direction substantially transverse to the plane. Smirmaul further discloses the cutting edge (20) is operable to engage intraocular tissue and penetrate there to create an incision in the intraocular tissue ("circular cutting blade 20 forms a circular incision in the anterior lens capsule"; column 2, lines 62-65).

Figure 3 shows the head portion (18) has a main portion having a radius, however, Smirmaul does not disclose an extension portion continuous with the main portion, having a second radius. Like Smirmaul, Anis discloses an instrument for incising intraocular tissue (removing the lens during cataract removal; column 2, lines 50-55). Unlike Smirmaul, Anis teaches a head portion (14) having a main portion (portion connected to shaft 18) having a first radius and at least one extension portion (not labeled; two extension portions begin at a point adjacent 15A and 15B) continuous with the main portion having a second radius different from the first radius (head portion 14 tapers, therefore, the main portion and extended portions have a different radius). Figure 1 further shows the head portion (14) includes spaced first and second ends (at a point adjacent the two extension portions) which define an opening there between.

Regarding claim 2, Figure 1 shows the second radius is smaller than the first radius (since head portion 14 tapers from the main portion to the extension portion).

Regarding claim 8, Figure 1 shows the head portion (14) is generally C-shaped and the extension portions comprise a proximal leg (15A) extending from a first end (not labeled) of the main portion and a distal leg (15B) extending from a second end (not labeled) of the main portion.

Regarding claim 9, Figure 2 shows the head portion (14) includes a second cutting edge (34) opposing the cutting edge (32).

Anis teaches the configuration of the head (14) contributes to the ability to produce cavitation (column 6, line 38) without damaging nearby tissue (column 5, lines 19-25). Therefore, to construct the head of Smirmaul with at least one extension portion as taught by Anis would have been obvious to one of ordinary skill in the art at the time the invention was made in order to be able to cut and remove certain tissue without damaging surrounding tissue.

Regarding claim 3, Smirmaul in view of Anis discloses the head portion (Anis; Figure 1, element 14) has a diameter of 2.0 mm in the widest configuration (Anis; column 9, lines 19-23); therefore, the first radius is about 1 mm. Since the second radius is smaller than the first radius, the second radius may be anywhere less than 1 mm, or "between about 0.25 to 2.0 mm." Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct a first radius between about 1.0 to 4.0 mm and a second radius between about 0.25 to 2.0 mm since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Regarding claims 5-7, Smirmaul in view of Anis disclose the handle (Anis; Figure 1, elements 11, 12, 19A, and 18 comprise the handle of hand piece 10) is connected to the head portion (14) at an intermediate point of the main portion (connected at 18 between first and second ends of the main portion). Smirmaul in view of Anis does not disclose the handle is connected to the head portion at an intermediate part of the extension portion, or at a junction of the main portion and the extension portion. Applicant has not disclosed that the location of the handle with respect to the head portion provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well if the handle was connected to the head portion at an intermediate part of the extension portion, or at a junction of the main portion and the extension portion. Therefore, it would have been obvious to modify the location of the handle with respect to the head portion of Smirmaul in view of Anis in order to obtain the invention as claimed in claims 6 and 7.

Regarding claim 13, Smirmaul in view of Anis disclose the cutting edge (Smirmaul; Figure 2, element 20) extends about 1 to 2 mm from the top part of the head portion (18; column 3, lines 22-23; see Figure 2 for illustration). The handle (12/16) is attached at the top of the head portion (see Figure 2), therefore, the handle (12/16) is connected to the head portion (18) at a location greater than about 0.3 mm above the cutting edge (20). Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to connect the handle to the head portion at a location greater than about 0.3 mm above the cutting edge, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Regarding claim 15, Smirmaul discloses an instrument for incising intraocular tissue (excision of the anterior lens capsule; column 1, lines 54-55) comprising a handle (Figure 1, elements 12/16), and a head portion (18). Figure 2 shows the head portion (18) defines a plane and has a cutting edge (20) that extends from the head portion (18) in a direction substantially transverse to the plane. Smirmaul further discloses the cutting edge (20) is operable to engage intraocular tissue and penetrate through to create a curvilinear incision in the intraocular tissue ("circular cutting blade 20 forms a circular incision in the anterior lens capsule", which is curvilinear since it follows the path of a curved line; column 2, lines 62-65).

Smirmaul does not disclose the head portion (18) is generally C-shaped. Like Smirmaul, Anis discloses an instrument for incising intraocular tissue (removing the lens during cataract removal; column 2, lines 50-55). Unlike Smirmaul, Anis teaches a generally C-shaped head portion (14) having a generally semicircular central portion (portion connected to shaft 18) having a first radius and first and second ends (at a point adjacent the two leg portions 15A and 15B), and proximal (15A) and distal (15B) legs continuous with the first and second ends of the central portion, respectively, the legs each having a second radius different from the first radius (head portion 14 tapers, therefore, the central portion and leg portions have a different radius).

Regarding claim 16, Figure 1 shows the second radius is smaller than the first radius (since head portion 14 tapers from the main portion to the extension portion).

Anis teaches the configuration of the head (14) contributes to the ability to produce cavitation (column 6, line 38) without damaging nearby tissue (column 5, lines 19-25). Therefore, to construct the head of Smirmaul generally C-shaped as taught by Anis would have been obvious to one of ordinary skill in the art at the time the invention was made in order to be able to cut and remove certain tissue without damaging surrounding tissue.

Regarding claim 17, Smirmaul in view of Anis discloses the head portion (Anis; Figure 1, element 14) has a diameter of 2.0 mm in the widest configuration (Anis; column 9, lines 19-23); therefore, the first radius is about 1 mm. Since the second radius is smaller than the first radius, the second radius may be anywhere less than 1 mm, or "between about 0.25 to 2.0 mm." Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct a first radius between about 1.0 to 4.0 mm and a second radius between about 0.25 to 2.0 mm since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Regarding claim 18, Smirmaul in view of Anis disclose the handle (Anis; Figure 1, elements 11, 12, 19A, and 18 comprise the handle of hand piece 10) is connected to the head portion (14) at an intermediate point of the main portion (connected at 18 between first and second ends of the main portion). Smirmaul in view of Anis does not disclose the handle is connected to the head portion at a location inward from an end of the proximal leg. Applicant has not disclosed the location of the handle with respect to the head portion provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well if the handle was connected to the head portion at a location inward from an end of the proximal leg. Therefore, it would have been obvious to modify the location of the handle with respect to the head portion of Smirmaul in view of Anis in order to obtain the invention as claimed in claim 18.

Regarding claim 19, Smirmaul discloses an instrument for incising intraocular tissue (excision of the anterior lens capsule; column 1, lines 54-55) comprising a handle (Figure 1, elements 12/16), and a head portion (18). Figure 2 shows the head portion (18) defines a plane and has a cutting edge (20) that extends from the head portion (18) in a direction substantially transverse to the plane. Smirmaul further discloses the cutting edge (20) is operable to engage intraocular tissue and penetrate there through to create an incision in the intraocular tissue ("circular cutting blade 20 forms a circular incision in the anterior lens capsule"; column 2, lines 62-65).

Figure 3 shows the head portion (18) has a first portion having a first radius, however, Smirmaul does not disclose a second portion continuous with the first portion and having a second radius different from the first radius. Like Smirmaul, Anis discloses an instrument for incising intraocular tissue (removing the lens during cataract removal; column 2, lines 50-55). Unlike Smirmaul, Anis teaches a head portion (14) having a first portion (portion connected to shaft 18) having a first radius and a second portion (not labeled; second portion begins at a point adjacent 15A) continuous with the first portion having a second radius different from the first radius (head 14 portion tapers, therefore, the first portion and second portion have a different radius).

Regarding claim 20, Figure 1 shows the second radius is smaller than the first radius (since head portion 14 tapers from the main portion to the extension portion).

Anis teaches the configuration of the head (14) contributes to the ability to produce cavitation (column 6, line 38) without damaging nearby tissue (column 5, lines 19-25). Therefore, to construct the head of Smirmaul with a second portion continuous with the first portion as taught by Anis would have been obvious to one of ordinary skill in the art at the time the invention was made in order to be able to cut and remove certain tissue without damaging surrounding tissue.

Regarding claim 21, Smirmaul in view of Anis discloses the head portion (Anis; Figure 1, element 14) has a diameter of 2.0 mm in the widest configuration (Anis; column 9, lines 19-23); therefore, the first radius is about 1 mm. Since the second radius is smaller than the first radius, the second radius may be anywhere less than 1 mm, or "between about 0.25 to 2.0 mm." Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct a first radius between about 1.0 to 4.0 mm and a second radius between about 0.25 to 2.0 mm since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Regarding claim 23, Smirmaul in view of Anis disclose the handle (Anis; Figure 1, elements 11, 12, 19A, and 18 comprise the handle of hand piece 10) is connected to the head portion (14) at an intermediate point of the main portion (connected at 18 between first and second ends of the main portion). Smirmaul in view of Anis does not disclose the handle is connected to the head portion at an intermediate portion of one of the first portion and the second portion. Applicant has not disclosed the location of the handle with respect to the head portion provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well if the handle was connected to the head portion at an intermediate portion of one of the first portion and the second portion. Therefore, it would have been obvious to modify the location of the handle with respect to the head portion of Smirmaul in view of Anis in order to obtain the invention as claimed in claim 23.

Regarding claim 24, Smirmaul discloses an instrument including a handle (12/16) and a head portion (18) attached to the handle (12/16), having a main portion with a radius. Smirmaul further discloses the head portion (18) includes a cutting edge (20) such that the head portion is operable to engage intraocular tissue and penetrate at least partially to create a first incision in the intraocular tissue ("circular cutting blade 20 forms a circular incision in the anterior lens capsule"; column 2, lines 62-65).

Smirmaul does not disclose at least one extension portion. Like Smirmaul, Anis discloses an instrument for incising intraocular tissue (removing the lens during cataract removal; column 2, lines 50-55). Unlike Smirmaul, Anis teaches a head portion (14) having a main portion (portion connected to shaft 18) having a first radius and at least one extension portion (two extension portions begin at a point adjacent 15A and 15B) continuous with the main portion having a second radius different from the first radius (head portion 14 tapers, therefore, the main portion and extended portions have a different radius). Figure 1 further shows the head portion (14) includes spaced first and second ends (at a point adjacent the two extension portions) which define an opening there between.

Anis teaches the configuration of the head (14) contributes to the ability to produce cavitation (column 6, line 38) without damaging nearby tissue (column 5, lines 19-25). Therefore, to construct the head of Smirmaul with at least one extension portion as taught by Anis would have been obvious to one of ordinary skill in the art at the time the invention was made in order to be able to cut and remove certain tissue without damaging surrounding tissue.

If the head portion (18) of Smirmaul is constructed with an extension potion as taught by Anis, then an incision with only one orientation may be made since the cutting edge is on the bottom side of the head portion (18). Therefore, it would have been obvious to one of ordinary skill in the art to reverse the orientation of the device (put the cutting edge on the top of the head portion 18) of Smirmaul in view of Anis in order to be able to create a second incision, having a second orientation, and thus resulting in a continuous flap, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. The preamble “A surgical kit” is given limited weight. However, it is obvious that a first and second instrument used to create first and second incisions in order to complete a single surgical procedure would comprise a "kit" since they both go hand in hand in order to complete an incision in the intraocular tissue.

Regarding claim 25, Smirmaul in view of Anis disclose a generally C-shaped head portion (14) including a generally semicircular central portion (portion connected to shaft 18) having a first radius, the central portion having first and second ends (at a point adjacent the two leg portions 15A and 15B), and proximal (15A) and distal (15B) legs continuous with the first and second ends of the central portion, respectively, the legs each having a second radius smaller than the first radius (since head portion 14 tapers from the central portion to the leg portions).

Regarding claim 26, Smirmaul in view of Anis disclose a head portion (14) including a first portion (portion connected to shaft 18) having a first radius, and a second portion (15A) continuous with the first portion and having a second radius smaller than the first radius (since head portion 14 tapers from the main portion to the extension portion).

6. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smirmaul in view of Anis as applied to the claims above, and further in view of Douvas et al. (Patent No. 3,990,453).

Smirmaul in view of Anis discloses a device as described above, however, Smirmaul in view of Anis does not disclose a serrated cutting edge. Douvas et al. disclose a cutting device for cataract surgery. Unlike Smirmaul in view of Anis, Douvas et al. disclose the cutting edge (Figure 8, element 134) may be serrated (132; column 4, lines 55-57) in order to facilitate the coring and fragmenting ability of the device (column

5, lines 6-10). Therefore, to construct the cutting edge of Smirmaul in view of Anis with serrations as taught by Douvas et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to facilitate making incisions in the tissue.

7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smirmaul in view of Anis as applied to the claims above, and further in view of Steinert (Patent No. 5,451,230).

Smirmaul in view of Anis discloses a device as described above. Smirmaul in view of Anis further discloses the handle (12/16) includes a generally horizontal portion extending along the plane of the head portion (18). However, Smirmaul in view of Anis does not disclose an angled potion extending at an angle relative to the horizontal portion. Steinert discloses a cataract disassembly device. Unlike Smirmaul in view of Anis, Steinert discloses an angled potion (Figure 2a, element 24) extending at an angle (α) relative to the horizontal portion (23) in order to ensure the instrument maintains contact with the nucleus (column 1, lines 43-46) during the procedure. Therefore, to provide an angled portion on the device of Smirmaul in view of Anis as taught by Steinert would have been obvious to one of ordinary skill in the art at the time the invention was made in order to ensure the cutting edge maintains contact with the tissue as the incision is being made, thus producing a continuous incision.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-

9062. The examiner can normally be reached on Monday through Thursday 7:30 a.m. - 5:00 p.m., alternate Fridays 7:30 a.m. - 4:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson MT
August 29, 2006

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
9/5/06